REMARKS

Applicants have amended certain claims above to overcome some of the Examiner's concerns regarding 35 USC §112 and to clarify and simplify the claims. New claims 86-88 have been added. Applicants have addressed the rejections under 35 USC §101, §112, and §103 below.

§101/Utility rejection

Claims 1, 4-17, 19-31, 33-35, and 85 are rejected under 35 USC §101. Applicants respectfully traverse this rejection.

The claims have met the three part test for utility under the Revised Interim Utility Guidelines Training Materials at http://www.uspto.gov/web/menu/utility.pdf which require a substantial, credible and specific use for the claimed invention. The Examiner has focused on the "specific" requirement in the present office action and Applicants will address that part of the test. They believe that the present claims also have shown that the present claims have credible and substantial uses, but will not go over those uses due to the nature of the Examiner's comments.

Applicants respectfully point out the Examiner is using an incorrect standard to view the utility of the present claims. The Examiner requires that the utility be "commensurate with the [scope of the] instant claims". Also, she requires that the asserted utility be "recited in the instant claims". Case law and the Revised Interim Utility Guidelines Training Materials of the PTO show that claims have utility if there is at least one utility as measured by what is disclosed in the specification or is known in the art. The utility does not need to be commensurate with the scope of the claims, nor does it need to be recited in the claims.

The Examiner stated in the May 31 Office Action:

> it is noted that the asserted utility (e.g., detecting what genes are expressed in particular organs, tissues, species and are associated with a disease) is not commensurate with the instant claims. Claim I, for example, recites that a user selects a number of random probe set identifiers and receives from a vendor a probe array comprising probes identified by the probe set identifiers. The instant method does not have specific utility because the specific utility is determined by a product produced by the method, i.e., an array, which does not have specific utility. The probe set identifiers randomly picked by a user do not tell the user what to use the array for. For example, one can randomly pick a set of probes, order them, and use the probes as a random size control for some other array. The utility of such an array is not specific. The examiner reiterates that although the claimed invention MAY have a substantial utility, the invention does not have a specific utility. Specifically, the result of the claimed method is providing a probe array which is determined on the basis of unknown probe set identifiers. In order for the result to be used for diagnostic purposes, one skilled in the art must be aware of a correlation between the information received from the method and a disease, disorder, trait, or condition to be diagnosed. Absent any disclosure about, for example, the connection of the array to a particular state, disease, trait, etc., the asserted utility is not specific. No such information is recited in the instant claims. Thus, for the reasons stated in the previous office action, the rejection of claims 1, 4-17, 19-31, 33-35, and 84 under 35 U.S.C. 101 is maintained for lack of patentable utility. (Emphasis added. See the present Office Action at pages 3 and 4).

Only one utility needs to be shown

The Examiner stated "the asserted utility . . . is not commensurate with the instant claims". The PTO and the law require that there be at least one utility, not that it be commensurate with the claims. See pages 3 and 4 of Revised Interim Utility Guidelines Training Materials at http://www.uspto.gov/web/menu/utility.pdf.

> It is assumed at this point in the analysis that the specification has been reviewed and an appropriate search of the claimed subject matter has been conducted. It is also assumed that some "utility" is disclosed in the specification or is recognized to be well-established in the art. The examiner should determine whether **any** asserted utility is specific and substantial, and if so, determine whether such asserted utility is credible. In determining credibility the examiner should consider whether or not there currently are similar or equivalent materials and/or procedures

available for achieving that utility. If there are, the utility is credible and no rejection under 35 U.S.C. §101 should be made.

Guidance for Various Examination Situations

I) a) For method claims that recite more than one utility, **if at least one** utility is credible, specific, and substantial, a rejection under 35 U.S.C. § 101 should **not** be made. If any utility in such a claim is not a specific and substantial credible utility, i.e., the claim encompasses at least one utility that does not meet the requirements of 35 U.S.C. §101, the rejection of the claim should be addressed under 35 U.S.C. § 112, first paragraph, scope of enablement.

b) For product claims that do not recite any utilities, disclosure or assertion of **one** specific, substantial and credible utility meets the criteria of 35 U.S.C. § 101. (Emphasis Added)

Additionally, case law shows that an Applicant can show at least one utility for a claimed invention. See *Juicy Whip v. Orange Bang*, 185 F. 3d 1364, 1366, 51 USPQ2d 1700, 1702 (Fed. Cir. 1999).

> Section 101 of the Patent Act of 1952, 35 U.S.C. § 101, provides that "[w]hoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof," may obtain a patent on the invention or discovery. The threshold of utility is not high: An invention is "useful" under section 101 if it is capable of providing some identifiable benefit. *See Brenner v. Manson,* 383 U.S. 519, 534, 86 S.Ct. 1033, 16 L.Ed.2d 69 (1966); *Brooktree Corp. v. Advanced Micro Devices, Inc.,* 977 F.2d 1555, 1571 (Fed.Cir.1992) ("To violate § 101 the claimed device must be totally incapable of achieving a useful result"); *Fuller v. Berger,* 120 F. 274, 275 (7th Cir.1903) (test for utility is whether invention "is incapable of serving any beneficial end").

See also, Applicants' arguments at pages 13-19 of the response filed April 10, 2006, as well as *Ex parte Lanham*, 121 USPQ 223 (Pat. Off. Bd. App. 1958). Consequently, §101 only requires one utility for a claimed invention.

Applicants showing of utility

Applicants have shown multiple specific utilities and it is clear that probe arrays have utility. Hundreds of patents have issued claiming arrays and hundreds of millions of dollars per year have been spent on arrays. They have use in nucleic acid hybridization (see paragraphs 61 and 62 of the present application), monitoring gene expression (paragraphs 65-67), determining genotype (see paragraph 61), disease detection (paragraphs 4 and 7), and specific arrays are currently being sold by the present Assignee for these utilities (paragraph 111). Consequently, there is ample evidence that a probe array has a broad spectrum of utility.

In supporting the utility rejection, the Examiner asserts that a user could construct an array with random probes, which has no utility. This is not the proper standard under 35 USC §101. The proper analysis is whether there is at least one utility as shown by the rules and case law above. As also shown above, there are many utilities that are clear from the present specification as well as being known to one of ordinary skill in the art.

The Examiner is also mistakenly requiring that the utility be present in the claims

The Examiner requires that the utility be stated in claims. However, case law shows that utility can be shown in the specification or by what is known in the art. The specific utility does not need to be recited in the claims. See generally *In re Brana,* 51 F.3d 1560, 34 USPQ2d 1436 (Fed. Cir. 1995).

Also, *Cross v. Iizuka*, 753 F2d. 1040, 224 USPQ 739 (Fed. Cir. 1985) states that the specification is the basis for the utility determination. See the following exemplary passages.

> Where a constructive reduction to practice is involved, as contrasted to an actual reduction to practice, a practical utility for the invention is determined by reference to, and a factual analysis of, the

> disclosures of the application. *Kawai v. Metlesics,* 480 F.2d 880, 178 USPQ 158 (CCPA 1973). Page 1044
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> Evidence of any utility is sufficient when the count does not recite any particular utility. *Nelson v. Bowler,* 626 F.2d 853, 856, 206 USPQ 881, 883 (CCPA 1980). *See also Rey-Bellet v. Englehardt,* 493 F.2d 1380, 181 USPQ 453 (CCPA 1974); *Knapp v. Anderson,* 477 F.2d 588, 177 USPQ 688 (CCPA 1973); *Blicke v. Treves,* 241 F.2d 718, 112 USPQ 472 (CCPA 1957). Page 1045
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> In *Nelson v. Bowler,* 626 F.2d 853, 206 USPQ 881 (1980), our predecessor court, the Court of Customs and Patent Appeals, stated that "[k]nowledge of the pharmacological activity of any compound is obviously beneficial to the public" and concluded that "adequate proof of any such utility constitutes a showing of practical utility." *Id.* at 856, 206 USPQ at 883. Page 1046

Consequently, the courts have been clear that the utility for the claimed invention is in the specification or the art and does not need to be specifically recited in the claims. Therefore, Applicants have shown that the present claims have utility as they show at least one specific utility which is disclosed in the specification and/or is known in the art. Therefore, the present §101 rejection should be withdrawn.

§112 Rejection

The Examiner has rejected claims 1-2, 4-9, 11-16, and 20 under 35 USC §112.

Applicants have amended claims 1 and 5 in response to the Examiner's helpful comments and have deleted "and responsive . . .nucleic acids." and "a second selection . . . additional users". Applicants have amended claim 20 to provide proper antecedent basis for the claim terms. Consequently, Applicants respectfully request that the Examiner reconsider and withdraw the §112 rejections.

§103 Rejections

Claims 1-2, 4-9, 11-16, 19-23, 25-30, 33-35, and 84 are rejected under 35 U.S.C. §103(a) over Anderson et al. (WO 01/80155) in view of Kincaid (US

2003/0162183). Claims 1, 5-8, 11-13, 15-16, 19-22, 25-27, 29-30, 33-35, and 84 are rejected under 35 U.S.C. §103(a) over Tekagawa et al. (US 2004/0067488 as a translation of WO 02/61646) in view of Kincaid (US 2003/0162183). Claims 2, 4, 14, and 28 are rejected under 35 U.S.C. §103(a) over Tekagawa et al. (US 2004/0067488 as a translation of WO 02/61646) in view of Cantor et al.(US 6,007,987) and further in view of Kincaid (US 2003/0162183). Claims 8-9, and 22-23 are rejected under 35 U.S.C. §103(a) over Tekagawa et al. (US 2004/0067488 as a translation of WO 02/61646) in view of Garner (US 2003/0033290) and further in view of Kincaid (US 2003/0162183).

Without addressing what is shown in Anderson et al., Tekagawa et al., Cantor et al., or Garner, Applicants assert that Kincaid does not show a key feature of sharing an array design between multiple users. The Examiner cites paragraph 5 for support (paragraph 50 is cited in some instances in the Office Action, but it appears that the Examiner meant 5), but a review of this section shows that information is shared between one user and an array designer. Not the "sharing" between multiple users as required by the current claims. For example,

> [0005] There is accordingly a need for an array design system and method that simplifies array design, that allows selective input of array design parameters by commercial array users, that can isolate such users from complex computational aspects of array design, and which allows quick and easy sharing of array design parameter information between commercial array users and array designers and manufacturers. The present invention satisfies these needs, as well as others, and overcomes the deficiencies found in the background art. (Emphasis added. See paragraph 5 of Kincaid.)

It is clear that this statement does not mean sharing array space between multiple users. Kincaid shows that his intent is to allow a user to provide input into selected variables that arise in the design and manufacture of an array. Paragraph 65 illustrates this point.

> [0065] The invention provides methods that allow the customers or end-users of arrays to participate in the array design process together with a commercial array vendor. The methods comprise selecting array design parameters by a customer, displaying and reviewing the selected parameters by the customer and, if desired, revising the parameter selections prior to transmitting or outputting the selected parameters to an

> array vendor or specialist for completion of the array design. The methods may further comprise selecting or providing, by a vendor, any array design parameters not provided by the customer, and creating a complete array design from the selected array design parameters.

Examples of the types of variables are shown in paragraphs 76 and 94. Nowhere in Kincaid is it shown that two or more users could or should share space on an array.

Consequently, Applicants respectfully request that the Examiner reconsider and withdraw the rejections based on §103 as the primary reference used to show "sharing" has been shown to be inapposite.

Conclusion

Applicants have shown that the present claims are useful und 35 USC §101 as they have at least one utility and that utility does not need to be present in the claims. Also, Applicants have simplified the claims to obviate the §112 rejection. Further, Applicants have shown that the only reference relied on for "sharing" does not apply to the presently claimed invention so that the rejections under 35 USC §103 should be withdrawn.

For these reasons, Applicants believe all pending claims are now in condition for allowance. If the Examiner has any questions pertaining to this application or felt that a telephone conference would in any way expedite the prosecution of the application, please do not hesitate to call the undersigned at (408) 731-5021.

The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account 01-0431.

Respectfully submitted,

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